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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,642	11/21/2003	Leon Fernando Garcia-Martinez	60117-86	3644

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EXAMINER	
BELYAVSKYI, MICHAIL A	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 10/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/719,642	GARCIA-MARTINEZ ET AL.	
	Examiner	Art Unit	
	Michail A. Belyavskyi	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) *4-36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-36 are pending.

2. Applicant's election of Group I, claims 1-3 and SEQ ID NO: 26,28,33,37,41, 45, 62 and 64 , in the reply filed on 07/06/06 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 4-36 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to nonelected inventions.

Claims 1-3 reads on an isolated antibody that can bind to a CD83 polypeptide, wherein said antibody comprises amino acid sequence SEQ ID NO: 26, 28, 33, 37, 41, 45, 62 or 64 *are under consideration in the instant application.*

3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention *to which the claims are directed.*

4. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. The filing date of the instant claims is deemed to be the filing date of the provisional application 60/428,130 , i.e. 11/21/02 , as the provisional application 60/331,958 fails to provide adequate support under 35 U.S.C. 112 for claims 1-3 of this application. If applicants disagree, applicants should present a detailed analysis as to why the claimed subject matter has clear support in the provisional application 60/331,958.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 3 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling an isolated antibody, comprising one specific V_H region, comprising 3 CDRs, i.e. CDR1, CDR2 and CDR3 and one specific V_L region comprising 3 CDRs, i.e. CDR1, CDR2, for example for disclosed G6G07 antibody, wherein V_H comprises CDR1(SEQ ID NO:28), CDRII (SIQ ID NO: 28) and CDRIII (SEQ ID NO 33) and V_L comprises CDR1(SEQ ID NO:37), CDRII (SIQ ID NO: 41) and CDRIII (SEQ ID NO 45) and CDR3 does not reasonably provide enablement for any isolated antibody, wherein said antibody comprising one of the sequences recited in claim 3. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims as written encompass the genus of antibodies that can specifically bind to a CD83 polypeptide.

Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized *In re Wands* (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). The factors most relevant to this rejection are the scope of the claim, the amount of direction or guidance provided, the limited working examples, the unpredictability in the art and the amount of experimentation required to enable one of skill in the art to practice the claimed invention.

Applicant disclosed several specific antibodies, for example G6G07, or 95G08 or 95F04 or specific V_L region or V_H each comprising 3 CDRs, that can bind to a CD83 polypeptide(see overlapping pages 39- 59 and page 96 of te instant Specification in particular).

The instant claim 3 recite an antibody with comprises either CDRI or CDRII or CDR III alone or in combination. However, it is well established in the art that the formation of an intact antigen-binding site generally requires the association of the complete heavy and light chain variable regions of a given antibody, each of which consists of three CDRs which provide the majority of the contact residues for the binding of the antibody to its target epitope. ((Paul, Fundamental Immunology, (textbook), 1999, under the heading "Immunoglobulins: Structure and Function,, pp. 37, 43, 58, 59)). The amino acid sequences and conformations of each of the heavy and light chain CDRs are critical in maintaining the antigen binding specificity and affinity which is characteristic of the parent immunoglobulin. It is expected that all of the heavy and light chain CDRs in their proper order and in the context of framework sequences which maintain their required conformation, are required in order to produce a human antibody having antigen-binding function and that proper association of heavy and light chain variable regions is required in order to form functional antigen binding sites. Even minor changes in the amino

acid sequences of the heavy and light variable regions, particularly in the CDRs, may dramatically affect antigen-binding function as evidenced by Rudikoff et al (Proc Natl Acad Sci USA 1982 Vol 79 page 1979). Rudikoff et al. teach that the alteration of a single amino acid in the CDR of a phosphocholine-binding myeloma protein resulted in the loss of antigen-binding function. It is unlikely that antibodies as defined by the claim which may contain less than the full complement of CDRs from the heavy and light chain variable regions in unspecified order have the required binding function. The specification provides no direction or guidance regarding how to produce antibodies as broadly defined by the claim. Undue experimentation would be required to produce the invention commensurate with the scope of the claim.

Thus, Applicant has not provided sufficient guidance to enable one skill in the art to use claimed any isolated antibody, wherein said antibody comprising one of the sequences recited in claim 3 in manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement. *In re Fisher*, 166 USPQ 18(CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute.

In view of the quantity of experimentation necessary, the unpredictability of the art, the lack of sufficient guidance in the specification, the limited working examples, and the limited amount of direction provided given the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:
A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e1) (1)an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published of a national application published under section 122(b) only if the international application designation the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

8. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by WO'9729781 or US Patent 5,766,570.

WO''781 teaches an isolated antibody that can bind to a CD83 polypeptide, comprising amino acid sequence that is 100 % identical to the claimed SEQ ID NO:97 (see entire document, Page 4 in particular and sequence alignment).

US' 570 teaches an isolated antibody that can bind to HB 15. It is noted that said polypeptide is 100% identical to the CD83 polypeptide of SEQ ID NO: 97 of the instant Application. (see attached sequence alignment.)

Claim 2 is included because the claimed functional limitation would be inherent properties of the referenced antibody, since the reference and claimed antibody can bind to the same CD83 polypeptide. Thus the reference antibody would inherently performed the intended use. If the prior art structure is capable of performing the intended use, then it meets the claim. When a claim recites using an old composition or structure (e.g. antibody that can bind to CD83) and the use is directed to a result or property of that composition or structure then the claim is anticipated. See MPEP 2112.02. Also, see Bristol-Myers Squibb Co. v. Ben Venue Laboratories, Inc. 58 USPQ2d 1508 (CA FC 2001); Ex parte Novitski 26 USPQ 1389 (BPAI 1993); Mehl/Biophile International Corp. V. Milgraum, 52 USPQ2d 1303 (Fed. Cir. 1999); Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999). Since the office does not have a laboratory to test the reference antibodies, it is applicant's burden to show that the reference antibodies do not decrease lymphocyte proliferation as claimed. See *In re Best*, 195 USPQ 430, 433 (CCPA 1977); *In re Marosi*, 218 USPQ 289, 292-293 (Fed. Cir. 1983); *In re Fitzgerald et al.*, 205 USPQ 594 (CCPA 1980).

The reference teaching anticipates the claimed invention.

9. Claims 1 and 2 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 6,068984.

US' 984 teaches an isolated antibody that can bind to HB 15. It is noted that said polypeptide is 100% identical to the CD83 polypeptide of SEQ ID NO: 97 of the instant Application. (see attached sequence alignment.)

Claim 2 is included because the claimed functional limitation would be inherent properties of the referenced antibody, since the reference and claimed antibody can bind to the same CD83 polypeptide. Thus the reference antibody would inherently performed the intended use. If the

prior art structure is capable of performing the intended use, then it meets the claim. When a claim recites using an old composition or structure (e.g. antibody that can bind to CD83) and the use is directed to a result or property of that composition or structure then the claim is anticipated. See MPEP 2112.02. Also, see Bristol-Myers Squibb Co. v. Ben Venue Laboratories, Inc. 58 USPQ2d 1508 (CA FC 2001); Ex parte Novitski 26 USPQ 1389 (BPAI 1993); Mehl/Biophile International Corp. V. Milgraum, 52 USPQ2d 1303 (Fed. Cir. 1999); Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999). Since the office does not have a laboratory to test the reference antibodies, it is applicant's burden to show that the reference antibodies do not decrease lymphocyte proliferation as claimed. See *In re Best*, 195 USPQ 430, 433 (CCPA 1977); *In re Marosi*, 218 USPQ 289, 292-293 (Fed. Cir. 1983); *In re Fitzgerald et al.*, 205 USPQ 594 (CCPA 1980).

The reference teaching anticipates the claimed invention.

10. Claims 1-3 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent Application 10/496,284.

US' 284 teaches an isolated antibody that can bind to CD83 polypeptide. US'284 teaches that said antibody comprises the same SEQ ID NOs as claimed in the instant claim 3, i.e. SEQ ID NOs: 26, 28, 33, 37, 41 , 45, 62 and 64.

Claim 2 is included because the claimed functional limitation would be inherent properties of the referenced antibody, since the reference and claimed antibody can bind to the same CD83 polypeptide. Thus the reference antibody would inherently performed the intended use. If the prior art structure is capable of performing the intended use, then it meets the claim. When a claim recites using an old composition or structure (e.g. antibody that can bind to CD83) and the use is directed to a result or property of that composition or structure then the claim is anticipated. See MPEP 2112.02. Also, see Bristol-Myers Squibb Co. v. Ben Venue Laboratories, Inc. 58 USPQ2d 1508 (CA FC 2001); Ex parte Novitski 26 USPQ 1389 (BPAI 1993); Mehl/Biophile International Corp. V. Milgraum, 52 USPQ2d 1303 (Fed. Cir. 1999); Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999). Since the office does not have a laboratory to test the reference antibodies, it is applicant's burden to show that the reference antibodies do not decrease lymphocyte proliferation as claimed. See *In re Best*, 195 USPQ 430, 433 (CCPA 1977); *In re Marosi*, 218 USPQ 289, 292-293 (Fed. Cir. 1983); *In re Fitzgerald et al.*, 205 USPQ 594 (CCPA 1980).

The reference teaching anticipates the claimed invention.

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 1-3 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 15-17 of copending Application No. 10/496,284. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 15-17 of copending Application No. 10/496,284 recites an antibody that can bind to a CD83. US'284 teaches that said antibody comprises the same SEQ ID NOs as claimed in the instant claim 3, i.e. SEQ ID NOs: 26, 28, 33, 37, 41 , 45, 62 and 64.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskyi whose telephone number is 571/272-0840. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571/272-0841.

The fax number for the organization where this application or proceeding is assigned is 571/273-8300

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MICHAIL BELYAVSKYI, PH.D.
PATENT EXAMINER

9/29/06